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(Li-Hsien Lin-Lauers)

Docket No.: 01017/40451C
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Brockhaus et al.

Application No.: 08/444,791

Confirmation No.: 5613

Filed: May 19, 1995

Art Unit: 1644

For: HUMAN TNF RECEPTOR

Examiner: Ronald B. Schwadron

PETITION UNDER 37 C.F.R. §1.181 WITH
REQUEST FOR REVIEW ON EXPEDITED BASIS

Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants hereby petition the Director under 37 C.F.R. §1.181 (and, to the extent necessary, under 37 C.F.R. §1.183) to review *on an expedited basis* and reverse the following actions of the Examiner in the above-identified application:

- (1) the election of species requirements in the Office Action mailed September 26, 2006 and the final Office Action mailed March 12, 2007; and
- (2) the finality of the Office Action mailed March 12, 2007.

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I. Statement of the Facts InvolvedA. The presently pending claims

The claims in the present application relate generally to DNA encoding fusion proteins comprising (1) a soluble fragment of a TNF receptor (TNFR) protein, having a molecular weight of either about 55 kD or about 75 kD, and (2) all of the domains of the constant region of a human immunoglobulin heavy chain other than the first domain of said constant region. The TNFR of about 55 kD is also referred to as the "p55 TNFR," while the TNFR of about 75 kD is also referred to as the "p75 TNFR." Exemplary claim 204 of the present application is set forth below:

204. A polynucleotide comprising two DNA subsequences, wherein the first subsequence encodes a soluble fragment of an insoluble TNF receptor protein, wherein said insoluble TNF receptor protein has a apparent molecular weight of either about 55 kilodaltons or about 75 kilodaltons as determined on a non-reducing SDS-polyacrylamide gel, and wherein the second subsequence encodes all of the domains of the constant region of a human immunoglobulin heavy chain other than the first domain of said constant region.

B. Brief history of parent U.S. Patent No. 5,610,279

The present application is a divisional of an issued patent, U.S. Patent No. 5,610,279 (the "'279 patent"). In the '279 patent, the claims were restricted into three groups: (I) protein and antibody, (II) DNA, vector and host, and (III) method of isolating proteins. Group I, protein claims, were elected, and claims relating to p55 TNFR fusion proteins eventually issued. Exemplary claim 1 of the '279 patent is set forth below:

1. A recombinant protein encoded by a polynucleotide which comprises two DNA subsequences, wherein the first subsequence encodes a soluble fragment of the insoluble TNF receptor protein, wherein said insoluble TNF receptor protein has a apparent molecular weight of about 55 kilodaltons as determined on a non-reducing SDS-polyacrylamide gel, and the second subsequence encodes all of the domains of the constant region of a human immunoglobulin heavy chain other than the first domain of said constant region.

Pending claim 204 of the present application and issued claim 1 of the '279 patent are closely parallel, except that claim 204 recites polynucleotides encoding p55 and p75 fusion proteins, and claim 1 recites p55 fusion proteins. The claims in the present

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application and the claims in the '279 patent were both rejected as assertedly obvious over the exactly the same art. In the March 12, 2007 Office Action in the present application, the claims were rejected for asserted obviousness over Schall et al.¹ (which was cited in the Office Action as disclosing p55 TNFR sequence) and Capon et al.² (which was cited in the Office Action as disclosing hybrid immunoglobulin fusion proteins). In the August 3, 1994 Office Action in the '279 patent, the claims were rejected, *inter alia*, for asserted obviousness over either Schall et al.³ or Wallach et al.⁴ (which was cited in the Office Action as disclosing soluble p55 TNFR) in combination with Capon et al.⁵ Among Applicants' arguments presented in the '279 patent was an argument that the claimed TNFR fusion proteins had unexpected properties.⁶

Similarly, the claims in the present application and the claims in the '279 patent were both rejected under the written description requirement of 35 U.S.C. §112.⁷ The claims of the '279 patent were allowed on August 23, 1996 in view of Applicants' arguments.

C. Brief relevant prosecution history of the present application

The present application was filed as a divisional application of the '279 patent to pursue a different restriction group, polynucleotide claims. The claims when filed related to polynucleotides encoding p55 TNFR and encoding p55 TNFR fusion proteins, as well as vectors and host systems. On August 22, 1996, Applicants filed an amendment adding generic claims to polynucleotides encoding TNFR fusion proteins (not specifying the p55 or p75 species), and a request for an interference with an issued patent.

Applicants received no actions from the Patent Office for over four years, despite filing six status inquiries. On August 24, 2000, Applicants filed a Withdrawal of

¹ Schall et al., Cell., 61(2):361-70 (1990).

² Capon et al., U.S. Patent No. 5,428,130.

³ Schall et al., Cell., 61(2):361-70 (1990).

⁴ Wallach et al., EP 308 378 A2

⁵ Capon et al., Int'l. Publication No. WO 89/02922, which corresponds to U.S. Patent No. 5,428,130.

⁶ Pages 12-13 of Applicants' amendment and response filed October 23, 1995 in the '279 patent; and pages 20-23 of Applicants' supplemental amendment and response filed January 19, 1996, together with Declarations I and II by Dr. Lesslauer, in the '279 patent.

⁷ See pages 3-6 of the March 12, 2007 Office Action in the present application and page 3 of the August 3, 1994 Office Action in the '279 patent, as well as page 2 (sections numbered 21-22) of the April 2, 1995 Office Action in the '279 patent.

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Mooted Request for Interference and amended the claims to recite the p55 and p75 TNFR species.

On June 1, 2001, Examiner Schwadron issued a restriction/election requirement that required two elections of species: (1) an election of one of the species of TNFR, p55 or p75, and (2) an election of one of the immunoglobulin species IgG1 or IgG3. Applicants elected the p55 TNFR species and IgG3 immunoglobulin species, with traverse, in a response filed August 9, 2001. Applicants filed another status inquiry on March 1, 2002.

An Office Action was mailed July 15, 2002, in which the election requirements were made final. The claims were rejected under the written description requirements of 35 U.S.C. §112, and for obviousness over Schall et al. and Capon et al., the same references cited during prosecution of the '279 patent and described above in section I.B. Applicants filed an amendment and response on January 14, 2003. In their response, Applicants argued that Schall et al. was not properly applied as prior art because there was no disclosure in Schall et al. extending beyond that which was already taught in Applicants' priority applications. Applicants' argument had been accepted by the Examiner in the '279 patent and the citation of Schall et al. had been withdrawn in the '279 patent.⁸

After a final office action was issued on March 26, 2003, Applicants, through their prior counsel, conducted an in-person interview with Examiner Schwadron on June 5, 2003. Applicants then filed an amendment and response on June 17, 2003 with a Rule 129 fee. The June 17, 2003 amendment added a number of claims, including claims to proteins. The June 17, 2003 response also included arguments that had not been made previously. For example, compare Applicants' argument with respect to written description on pages 4-5 of Applicants' January 14, 2003 response with corresponding pages 9-19 of Applicants June 17, 2003 response. The Applicants pointed to many different portions of the specification to support their argument that the written description requirement was satisfied, stating that "In view of the foregoing disclosure, none of which was referenced by the Patent Office in making the rejection, it is submitted that the claimed subject matter is more than adequately described in the specification [emphasis omitted]."⁹

⁸ See page 4 of April 24, 1995 Office Action in the '279 patent.

⁹ See page 16 of Applicants' amendment and response filed June 17, 2003 in the present application.

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On September 23, 2003, another restriction/election requirement was issued. This Office Action stated that the claims included four independent and distinct groups: (I) DNA, (II) methods of making DNA, (III) protein, and (IV) methods of making protein, and also stated that Applicants had constructively elected restriction group I (DNA). This Office action also required new elections of species: (1) an election of one of the species IgG, IgA, IgM or IgE, and (2) an election of one of the species IgG1 or IgG3. Although the pending claims at this time recited both p55 and p75, there was *no requirement to elect p55 or p75 TNFR species, nor was there any mention that the p55 species had been constructively elected.*

After a submission and payment of the fee under Rule 129, the Examiner may exercise his discretion to permit a switch of the elected group of claims under examination. The September 23, 2003 Office Action requesting that Applicants elect again between IgG1 and IgG3 species was an example of the Examiner exercising such discretion. This time, Applicants elected the IgG1 species,¹⁰ and timely traversed the restriction/election requirement on March 22, 2004. On June 9, 2004, the Examiner issued a notice of incomplete reply that required an identification of the IgG species elected and a listing of claims readable on such species. Subsequently, responsibility for prosecution of this application was transferred to the undersigned firm.

On November 18, 2004, Applicant's representatives from the undersigned firm met the Examiner for an in-person interview, during which Applicants raised with the Examiner the possibility of switching the elected group from polynucleotides to proteins. During the interview, protein claims directed to fusion proteins comprising soluble fragments of the p75 species of TNFR were discussed. The official Interview Summary states that Applicants and Examiner "Discussed pending rejections and evidence to overcome said rejections."

On December 9, 2004, Applicants submitted an amendment replacing all pending claims with claims to the p75 species of fusion protein. In the amendment, Applicants specifically noted the fact that the restriction requirement mailed September 23, 2003 did not require an election between the p55 and p75 species.¹¹ Applicants' remarks also

¹⁰ See page 2 of Applicants' amendment and response filed March 22, 2004 in the present application.

¹¹ See page 14 of Applicants' amendment and response filed December 9, 2004 in the present application.

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stated: "It was the Examiner's position during the interview that Capon, if combined with other art teaching the TNF receptor sequence, would render obvious claims to TNF receptor-Ig fusion proteins."¹² To pre-emptively address the Examiner's position, and therefore advance prosecution, Applicants supplied evidence of unexpected properties of the claimed p75 TNFR fusion proteins.¹³ Applicants also re-affirmed their election of the IgG1 immunoglobulin species and identified all claims as reading upon the elected immunoglobulin species.¹⁴

Subsequently, Applicants received two more communications from the Examiner relating to the voluntary sequence listing that Applicants had submitted in order to expedite prosecution. On September 20, 2005, Applicants' representatives met the Examiner for another in-person interview, during which Applicants discussed withdrawing their request to switch the claims to a different group, so that polynucleotide claims would be reinstated.¹⁵ On October 7, 2005, Applicants submitted an amendment replacing all pending claims with polynucleotide claims encoding the p75 TNFR species of fusion protein.

On January 25, 2006 another restriction requirement was issued, which stated that the claims included two independent and distinct groups: (I) DNA and (II) method of making protein, and stated that Applicants had constructively elected group I (DNA). It also required an election of one of the sequences SEQ ID NO: 12, 8, or 10, each of which are part of the p75 TNFR sequence, and stated that "Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits." This restriction requirement contained *no indication that an election was required between p55 and p75 species, or that the p55 species had been constructively elected.* On February 22, 2006, Applicants elected SEQ ID NO:12 and timely traversed the election requirement. On June 22, 2006, Applicants' representatives again met the Examiner for an in-person interview during which Dr. Lesslauer, one of the inventors, discussed certain art and unexpected results relating to the p75 species of fusion protein polynucleotides.¹⁶

¹² See page 17 of Applicants' amendment and response filed December 9, 2004 in the present application.

¹³ See pages 16-18 of Applicants' amendment and response filed December 9, 2004, together with a Declaration of Dr. Lesslauer and other evidence, in the present application.

¹⁴ See pages 13-14 of Applicants' amendment and response filed December 9, 2004 in the present application.

¹⁵ See page 12 of Applicants' amendment and response dated October 7, 2005 in the present application.

¹⁶ See Page 16 of Applicants' amendment and response filed November 22, 2006 in the present application

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On September 26, 2006 the Examiner issued, *for the first time since Applicants' Rule 129 submission over three years earlier*, a communication indicating that an election between the p55 and p75 species was required and stating that p55 had been constructively elected. Applicants' prior elections with respect to the p75 species were held in abeyance until the search would be extended to the p75 species.

On October 24, 2006, Applicants conducted a telephonic interview with the Examiner. During the interview, Applicants expressed their surprise that the issue of p55 vs. p75 species was being raised at this time, when there had been no indication that the p75 species was a concern in either of the last two restriction requirements, in other written communications, or during multiple prior in-person interviews in the last two years.¹⁷ As noted in Applicants' subsequent amendment, the "Examiner suggested that Applicants add a few claims encompassing the p55 species and invited Applicants to explain their rationale for examining the p75 species."¹⁸

Applicants complied with the Examiner's request in an amendment filed on November 22, 2006. The amendment added generic claims reciting the p55 and p75 TNFR species that paralleled the issued '279 patent claims, because Applicants' believed such claims to be patentable.¹⁹ Applicants also noted that "The Examiner confirmed during the October 24, 2006 telephonic interview that he would be conducting an updated prior art search, even if the p55 species were examined, because the last substantive office action in this application was mailed over three years ago."²⁰

On March 12, 2007 the Examiner issued the first office action on the merits after Applicants' Rule 129 submission. The Office Action stated that p55 TNFR species had been constructively elected. It also stated, *for the first time since Applicants' Rule 129 submission over three years earlier*, that the IgG3 species had been constructively elected. The constructive election the Examiner referred to was an *election made nearly six years ago*, in Applicants' paper filed August 9, 2001: "As per the Office Action mailed 7/15/02, paragraph 1, the species under consideration is DNA encoding the 55 kD TNFBP and DNA

¹⁷ See pages 14-15 of Applicants' amendment and response filed November 22, 2006 in the present application.

¹⁸ See page 15 of Applicants' amendment and response filed November 22, 2006 in the present application.

¹⁹ See page 18 of Applicants' amendment and response filed November 22, 2006 in the present application.

²⁰ See page 17 of Applicants' amendment and response filed November 22, 2006 in the present application.

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encoding IgG3.²¹ All claims other than the small number of new claims encompassing the p55 TNFR species, which were added at the Examiner's suggestion, were withdrawn from consideration. This first office action was also a *final* office action.

Applicants telephoned the Examiner to request that he make the March 12, 2007 decision regarding the election of species requirements final, to clarify that Applicants were permitted to petition the decision under 37 C.F.R. §1.144. The Examiner stated that he did not feel he needed to make the decision on election final because he was relying on the constructive election which had already been made final in the July 15, 2002 Office Action.

II. Relief Requested

Because of the finality of the outstanding Office Action, Applicants respectfully request that the Director consider this petition on an *expedited basis*, so that if a decision is rendered in Applicants' favor matters can be corrected before prosecution progresses too far.

Applicants also request under 37 C.F.R. §1.183 that the Commissioner suspend or waive the rules, if necessary, to allow Applicants to petition the Examiner's March 12, 2007 decision on the election requirements, even though such decision was not explicitly made final (see 37 C.F.R. §1.144).

Applicants respectfully request that the Director render a decision:

(1) directing the Examiner to withdraw the election requirement between the p55 and p75 species of TNF-R, to examine all pending claims relating to the p55 and p75 species, to withdraw the pending March 12, 2007 Office Action, and to issue a new, non-final office action;

(2) directing the Examiner to re-instate Applicants' election of IgG1 immunoglobulin species, to examine all pending claims relating to the IgG1 species, to withdraw the pending March 12, 2007 Office Action, and to issue a new, non-final office action; and

²¹ See page 2 of the Office action mailed March 12, 2007 in the present application.

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(3) directing the Examiner to withdraw finality of the Office Action mailed March 12, 2007 as premature.

III. Statement of Reasons That Requested Relief Should Be Granted

A. The Election Requirements Were Improper

1. The election requirement between p55 and p75 TNFR species was waived in the two restriction/election requirements after Applicants' Rule 129 submission

The Examiner waived the election requirement between the p55 and p75 TNFR species by (1) failing to re-state or refer to the requirement in any of the six official communications, including two restriction/election requirements, mailed subsequent to Applicants' Rule 129 submission of June 17, 2003, and (2) stating in the January 25, 2006 communication that a p75 TNFR sequence would be the subject of "prosecution on the merits." It was improper for the Examiner to raise the species election for the first time in the September 26, 2006 office action, more than three years after Applicants' Rule 129 submission, and after Applicants explicitly reminded the Examiner that no election had been required between p55 and p75.

According to MPEP § 707.07(e):

The examiner should note in every letter all the requirements outstanding against the application. *Every point in the prior action of an examiner which is still applicable must be repeated or referred to, to prevent the implied waiver of the requirement.* [emphasis added]

Even though Applicants reminded Examiner in remarks filed December 9, 2004²² that there had been no requirement for election between p55 or p75 TNFR species, the Examiner *never referred to any election requirement between p55 and p75 species* during any of the three in-person interviews conducted since November 2004 or in either of the restriction/election requirements issued after Applicants Rule 129 submission on June 17, 2003. This failure to repeat or refer to the election requirement between p55 and p75 species, despite repeating or referring to other prior restriction/election requirements.